CONTINUATION PATENT APPLICATION OF

BRUCE C. JOHNSON

ENTITLED

NASAL DILATOR

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NASAL DILATOR

BACKGROUND OF THE INVENTION

This is a continuation of Application Serial No. 08/183,916, filed January 19, 1994, now U.S. patent # 5533499, which is a continuation of Application Serial No. 08/048,589, filed April 16, 1993, now abandoned, which is a continuation of Application Serial No. 07/884,626, filed May 15, 1992, now abandoned, which is a continuation of Application Serial No. 07/712,508, filed June 6, 1991, now abandoned.

This invention relates generally to the field of devices for the treatment of malformations. In particular, the present invention is a nasal dilator for preventing outer wall tissue of nasal passages of a nose from drawing in during breathing.

A portion of the human population has some malformation of the nasal passages which makes breathing difficult. Example of such malformations are a deviated septum and swelling due to allergic reactions. The lower portion of the nostril, immediately above the entrance to the nostril, is known as a vestibule. The vestibule tapers inwardly to a narrowed neck-like area called the ostium internum. Above the ostium internum the nasal passages widen out again. Nasal obstructions commonly occur at the ostium in individuals who have swelling due to allergic reactions, a deviated septum or similar condition, to the point that the ostium may be substantially blocked. Commonly, the lateral wall (i.e., the outer wall tissue of the nasal passage) at the ostium is loose with the result that the outer wall tissue draws in during the process of inhalation to substantially block the passage of air through the nasal passage. The drawing in of the outer wall tissue act as a "check valve" to block air flow during in-breathing.

Blockage of the nasal passages is obviously an inconvenience to persons who experience it. In particular, sustained mouth breathing over a long

period of time may cause lung irritation due to the inhalation of foreign particles that would otherwise be filtered if the breath had been passed through the nose. Blockage of the nasal passages is particularly uncomfortable at night, since it is uncomfortable for many people who have such a problem to breathe through the mouth while asleep. Nasal blockage can lead to sleep disturbances and irregularities, since a person with such a condition may wake often because he/she is not inhaling sufficient quantities of oxygen.

The most common approach to a serious and chronic nasal blockage problem as described above is a surgical attempt to correct the malformation of the nasal passages. However, surgery is expensive and may not ultimately correct the problem.

As an alternative to surgery, nasal dilators for aiding breathing through the nose are generally known. United States Patent No. 4,414,977 to Rezakhany discloses one such nasal dilator. The nasal dilator includes generally elongated top and bottom rings which are spaced apart and connected together by a rear strut and a front strut. The front strut is longer than the rear strut and includes a bend therein formed at a position close to the front end of the bottom ring. When in place in the nasal passage, the top ring fits in the ostium within the nostril to prevent the tissue from being drawn in during inhalation, and to reduce extra flow resistance during exhalation. The bottom ring fits above the entrance to the nostril and serves to stabilize the position of the top ring within the nasal passage. One of these nasal dilators must be inserted into each nasal passage to provide unobstructed breathing.

However, these nasal dilators are not always effective since they are uncomfortable to wear. Because the nasal dilators must be inserted within the nasal passages they may cause irritation and itching. In addition, these nasal dilators must be custom-made to fit each nasal passage of an individual.

It is evident that there is a continuing need for improved nasal dilators for preventing outer wall tissue of nasal passages of a nose from drawing in during breathing. Specifically, there is a need for a nasal dilator that can provide effective relief without the need of inserting an object within the nasal passage. Moreover, there is a need for a nasal dilator that can be worn at night when the nasal blockage problem is most acute and most uncomfortable. The nasal dilator should be of efficient design and relatively uncomplicated and provide effective stabilization of the outer wall tissue of the nasal passages to provide effective relief from nasal blockage during inhalation. In addition, the nasal dilator should provide this effective stabilization without undue discomfort to the wearer.

SUMMARY OF THE INVENTION

The present invention is a nasal dilator for preventing outer wall tissue of nasal passages of a nose from drawing in during breathing. The nasal dilator comprises a truss member having a first end region adapted to engage the outer wall tissue of a first nasal passage. A second end region of the truss member is configured to engage the outer wall tissue of a second nasal passage. The first and second end regions of the truss member are coupled to one another by an intermediate segment. The intermediate segment is configured to traverse a portion of the nose located between the first and second nasal passages. The truss member, when in place, acts to stabilize the outer wall tissue and thereby prevent the outer wall tissue of the first and second nasal passages from drawing in during breathing.

The truss member includes a flexible strip of material that defines the first and second end regions and the intermediate segment of nasal dilator. A first resilient band is secured to a first side of the strip of material adjacent a first edge of the material. A second resilient band spaced from the first resilient band is secured to the first side of the strip of material adjacent a second edge

thereof. The first and second resilient bands are oriented generally parallel to one another and substantially parallel to the longitudinal extent of the strip of material.

Each of the first and second resilient bands includes a plurality of grooves that extend substantially parallel to the respective resilient band. The grooves create areas of reduced material to enhance the flexibility of the first and second resilient bands in a direction perpendicular to the grooves. In addition, each of the first and second resilient bands includes first and second angled ends. The first and second angled ends extend towards the first side of the strip of material and help to prevent the first and second resilient bands from readily separating from the strip of material when the truss member is flexed. The resiliency of the first and second resilient bands prevent the outer wall tissue of the first and second nasal passages from drawing in during breathing.

The truss member further includes an adhesive substance located on a second side of the flexible strip of material. The adhesive substance acts to releasably secure the truss member to the outer wall tissue of the first and second nasal passages. First and second release liners cover the adhesive substance on the first and second end regions. The first and second release liners are readily removable from the strip of material to expose the adhesive substance and permit the truss member to be secured to the outer wall tissue of the first and second nasal passages.

This nasal dilator is of efficient design and effectively prevents the outer wall tissue of the first and second nasal passages of the nose from drawing in during breathing. In addition, the nasal dilator provides effective relief of nasal blockage during inhalation without the irritation and discomfort normally associated with nasal dilators that are inserted within the nasal passages. Moreover, this nasal dilator can be worn at night when the inhalation nasal

blockage problem is most acute, without the anxiety and inconvenience normally associated with custom made, internally worn nasal dilators.

BRIEF DESCRIPTION OF THE DRAWINGS

FIG. 1 is perspective view of a portion of a face with a nasal dilator in accordance with the present invention secured to a nose.

FIG. 2 is an exploded perspective view showing the components of the nasal dilator in accordance with the present invention.

FIG. 3 is a perspective view similar to FIG. 1 with the nasal dilator in accordance with the present invention removed from the nose.

FIG. 4 is a sectional view taken along line 4-4 in FIG. 3 showing the nose in a state wherein no appreciable flow of air is occurring in the nasal passages.

FIG. 5 is a sectional view similar to FIG. 4 showing the state of the nose during inhalation.

FIG. 6 is a sectional view taken along line 6-6 in FIG. 1 showing the state of the nose during inhalation with the nasal dilator in accordance with the present invention secured thereto.

DETAILED DESCRIPTION OF THE PREFERRED EMBODIMENTS

A nasal dilator 10 in accordance with the present invention is illustrated generally in FIG. 1. The nasal dilator 10 is shown secured to a nose 12 of a wearer 14.

As seen in FIG. 2, the nasal dilator 10 comprises a truss member 16 including a flexible strip of material 18 having a first end region 20 and a second end region 22 coupled to the first end region 20 by way of an intermediate segment 24. The width of the intermediate segment 24 is less than the width of the first and second end regions 20 and 22. The flexible strip of material 18 is preferably formed of an interwoven piece of fabric that allows the

skin of the nose 12 to breathe to maximize comfort and minimize irritation. As an alternative, the strip of material 18 may be formed of a plastic film.

The truss member further includes resilient means 26 secured to a first side 28 of the strip of material 18. The resilient means 26 includes a first resilient band 30a secured by a first adhesive member 31a to the first side 28 of the strip of material 18. The first resilient band 30a is secured to the strip of material 18 adjacent a first edge 32 of the intermediate segment 24. In addition, a second resilient band 30b, spaced from the first resilient band 30a, is secured by a second adhesive member 31b to the first side 28 of the strip of material 18. The second resilient band 30b is secured to the strip of material 18 adjacent a second edge 36 of the intermediate segment 24. The first and second resilient bands 30a and 30b are oriented generally parallel to one another and substantially parallel to the longitudinal extent of the flexible strip of material 18. Each of the first and second adhesive members 31a and 31b is formed of an adhesive material such as double sided adhesive, foam tape.

Each of the first and second resilient bands 30a and 30b includes a plurality of grooves 38a and 38b, respectively, that extend substantially parallel to the respective resilient band 30a and 30b. As seen best in FIG. 2, the grooves 38a and 38b are formed in the exposed sides of the first and second resilient bands 30a and 30b (i.e., the sides of the first and second resilient bands 30a and 30b opposite that to which the first and second adhesive members 31a and 31b are secured). The grooves 38a and 38b create areas of reduced material to enhance the flexibility of the first and second resilient bands 30a and 30b in a direction perpendicular to the plurality of grooves 38a and 38b. In addition, each of the first and second resilient bands 30a and 30b includes first angled ends 40a and 40b, respectively, and second angled ends 42a and 42b, respectively. The first and second angled ends 40a,b and 42a,b extend towards the first side 28 of the strip of material 18 and help to prevent the first and second resilient bands

30a and 30b from readily separating from the strip of material 18 and the first and second adhesive members 31a and 31b when the truss member 10 is flexed. The first and second resilient bands 30a and 30b are formed of a plastic material.

As seen in FIG. 2, a second side 44 of the strip of material 18 includes a layer of an adhesive substance 46 that extends over the first and second end regions 20 and 22 and the intermediate segment 24. The adhesive substance 46 is bio-compatible with the skin of the nose 12. A padded element 48 is secured to the median of the intermediate segment 24 via the adhesive substance 46. Readily removable, first and second release liners 49 and 50, respectively, cover the adhesive substance 46 on the first and second end regions 20 and 22, respectively, of the strip of material 18. The first and second release liners 49 and 50 cover the adhesive substance 46 and remain in place on the strip of material 18 until the nasal dilator 10 is to be used. The first and second release liners 49 and 50 also include extensions 51 and 52, respectively, that cover the padded element 48 and further act to protect the padded element 48 until the nasal dilator 10 is to be secured to the nose 12 of a wearer 14.

As seen in FIGS. 3 and 4, the nose 12 includes a first nasal passage 54, a second nasal passages 56 and a portion of the nose 12 known as the bridge 58 located between the first and second nasal passages 54 and 56. FIG. 4 shows the state of the first and second nasal passages 54 and 56 when no appreciable flow of air is occurring through the nasal passages 54 and 56. Due to a malformation, such as a deviated septum or swelling due to allergic reactions, outer wall tissue 60 and 62 of the first and second nasal passages 54 and 56, respectively, tends to be drawn in (i.e., collapse) during inhalation (see FIG. 5). This drawing in during inhalation is caused by reduced air pressure within the first and second nasal passages 54 and 56 as a result of an increase in air velocity as the in drawn breath travels through the first and second nasal passages 54 and 56. The portion (i.e., the ostium) of the outer wall tissue 60 and

62 drawn in during inhalation is that located between the nasal cartilage 64 (shown in dashed lines in FIGS. 1 and 3) and the entrance to the nasal passages 54 and 56. This drawing in of the outer wall tissue 60 and 62 causes nasal blockage. The nasal dilator 10 of the present invention remedies this problem.

To secure the nasal dilator 10 to the nose 12, the first and second release liners 49 and 50 are removed from the flexible strip of material 18 to expose the adhesive substance 46. As seen in FIGS. 1 and 6, the nasal dilator 10 is placed on the exterior of the nose 12 such that the intermediate segment 24 traverses the bridge 58 of the nose 12 and the first and second end regions 20 and 22 contact the outer wall tissue 60 and 62 of the first and second nasal passages 54 and 56. The adhesive substance 46 on the first and second end regions 20 and 22 releasably secures the truss member 16 to the outer wall tissue 60 and 62 of the first and second nasal passages 54 and 56. As seen in FIG. 6, the padded element 48 creates an absorbent adhesive void between the truss member 16 and the bridge 58. This absorbent adhesive void absorbs moisture due to perspiration or the like. With the nasal dilator 10 in place about the nose 12, the resiliency of the first and second resilient bands 30a and 30b (i.e., the tendency of the resilient bands to return to their normally planar state shown in FIG. 2) acts to stabilize the outer wall tissue 60 and 62 and thereby prevents the outer wall tissue 60 and 62 of the first and second nasal passages 54 and 56 from drawing in during breathing (i.e., during inhalation). In addition, the flexibility of the strip of material 18 and the first and second adhesive members 31a and 31b, the resiliency of the first and second bands 30a and 30b, and the flexibility of the first and second bands 30a and 30b due to the grooves 38a and 38b, all allow the nasal dilator 10 to closely conform to the curves of the nose of each individual wearer.

This nasal dilator 10 is of efficient design and effectively prevents the outer wall tissue 60 and 62 of the first and second nasal passages 54 and 56 of the nose 12 from drawing in during breathing. In addition, the nasal dilator 10 provides effective relief of nasal blockage during inhalation without the irritation and discomfort normally associated with nasal dilators that are inserted within the nasal passages. Moreover, this nasal dilator 10 can be worn at night when the inhalation nasal blockage problem is most acute, without the anxiety and inconvenience normally associated with custom made, internally worn nasal dilators.

Although the present invention has been described with reference to preferred embodiments, workers skilled in the art will recognize that changes may be made in form and detail without departing from the spirit and scope of the invention.